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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO HEADQUARTERS

IN RE FIBROGEN, INC., SECURITIES LITIGATION

No. 3:21-cv-02623-EMC

CLASS ACTION

MOTION OF DEFENDANT K. PEONY YU, M.D. TO DISMISS CONSOLIDATED COMPLAINT AND JOINDER IN MOTION TO DISMISS FILED BY OTHER DEFENDANTS

Date: April 28, 2022
Time: 1:30 p.m.
Courtroom: 5
Judge: Hon. Edward M. Chen

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NOTICE OF MOTION AND MOTION

TO PLAINTIFFS AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that on Thursday, April 28, 2022, at 1:30 p.m., or as soon thereafter as counsel may be heard, in Courtroom 5 of this Court, located at 450 Golden Gate Avenue, 17th Floor, San Francisco, California, before the Honorable Edward M. Chen, United States District Judge, defendant K. Peony Yu, M.D. will and hereby does (i) move this Court to dismiss, with prejudice, all purported claims asserted against her in Plaintiffs' Consolidated Class Action Complaint for Violations of the Federal Securities Laws, filed October 29, 2021 (ECF 91) ("CAC") and (ii) join in the motion to dismiss filed today by FibroGen, Inc. and the other individual defendants, ECF No. 107 ("FibroGen Motion" or "FibroGen Mot.").

This motion and joinder is made under Rules 9(b) and 12(b)(6) of the Federal Rules of Civil Procedure, and the Private Securities Litigation Reform Act ("PSLRA"), on the grounds that the CAC fails to state a claim against Dr. Yu.

This motion is based on this notice of motion and motion, the memorandum that follows, the FibroGen Motion, the request for judicial notice and supporting declaration of Alexander J. Kasner filed together with the FibroGen Motion, and all pleadings and records filed in this action.

ISSUES TO BE DECIDED

1. Should Count I, Plaintiffs' claim under Section 10(b) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5, be dismissed because the CAC fails to allege facts showing that the statements allegedly made by Dr. Yu were materially false or misleading?

2. Should Count I be dismissed because the CAC fails to allege facts creating a strong inference of scienter as to Dr. Yu, as required by *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324 (2007)?

3. Should Plaintiffs' control person claims be dismissed because Plaintiffs have not stated any claims of primary violations against Dr. Yu and because Plaintiffs' allegations demonstrate that Dr. Yu was not a control person at least once she ceased to be FibroGen's Chief Medical Officer and then ceased to be an employee of FibroGen?

SUPPORTING MEMORANDUM

I. INTRODUCTION

As explained in the FibroGen Motion, which Dr. Yu joins, anemia can be a serious medical condition, patients suffering from chronic kidney disease commonly have anemia, and the standard treatments – blood transfusions and epoetin alfa — have serious drawbacks. Roxadustat is a first-in-class pill that can improve hemoglobin levels. Its efficacy is beyond dispute. Its safety, as compared to epoetin alfa or placebo, is a closer question. Though Plaintiffs allege otherwise, this case is not about efficacy. It is about safety: about what Defendants did and did not say about pooled safety studies submitted with their New Drug Application ("NDA") to the Food and Drug Administration.

Plaintiffs allege that the Defendants committed securities fraud by making 96 false or misleading statements during the Class Period from December 20, 2018 to July 15, 2021. They allege that Dr. Yu made 21 of those statements, from December 20, 2018, to May 7, 2020. But their allegations fail to meet the PSLRA's exacting standards for pleading either falsity or scienter.

Falsity: Dr. Yu's alleged misstatements fall into these categories: the efficacy of roxadustat; the likelihood that roxadustat would avoid a "black box" label if approved; the "non-inferiority margin" that the FDA might apply; and the safety of roxadustat.

Efficacy: Plaintiffs allege that Dr. Yu expressed her belief that study results demonstrated roxadustat's efficacy. But publicly stated interpretation of clinical study results are opinion and cannot state a claim unless Plaintiffs allege provable facts demonstrating the opinion is both objectively and subjectively false. The CAC does not allege facts suggesting that Dr. Yu did not believe what she said. Nor does the CAC plead facts showing objective falsity, even in hindsight. The FDA says roxadustat's "efficacy is not in question" as "[a]ll studies … demonstrated efficacy."

Black box: Dr. Yu said she hoped and had confidence that roxadustat would avoid a "black box" label, but she cautioned that the labelling decision was beyond FibroGen's control and in the hands of the FDA. Others added, "this is a decision for the regulators." Dr. Yu's statements were opinions and forward-looking statements accompanied by cautionary remarks, hence not actionable.

"Non-inferiority margin": Plaintiffs allege that Dr. Yu said the conventional non-inferiority margin, widely published and previously used by the FDA in assessing cardiovascular safety, was

1.3. The CAC does not allege anything showing her opinion to be false, let alone not believed by her. Defendants repeatedly cautioned that while they were discussing the non-inferiority margin with the FDA, no agreement had been reached. As late as July 2021, a high FDA official said the choice of a non-inferiority margin was "arbitrary" and "1.3 is reasonable."

Safety: Dr. Yu's alleged statements about safety are her opinions interpreting individual studies and the pooled safety analyses. Nothing suggests Dr. Yu did not believe what she said. Plaintiffs allege instead that optimism about safety was unwarranted because secretly based on methods of analysis that, in Plaintiffs' view, were illegitimate because chosen after the data were unblinded. The CAC and the documents it cites rebut that theory. Defendants stated publicly that FibroGen was having an ongoing dialogue with the FDA about analytical methodology and that, at the "pre-NDA meeting," after unblinding, the FDA accepted FibroGen's proposed analyses. The market thus knew that discussions about statistical analyses FibroGen and which ones the FDA wanted to see in the NDA continued after unblinding. Plaintiffs cannot base a fraud claim on disagreement with how Defendants chose to interpret the results of studies.

Scienter: Individually or holistically, the CAC's allegations do not satisfy the PSLRA.

CW3's allegations: Speculation by a non-scientist who merely sat in the audience at an unidentified meeting and heard unspecified statements raises no inference of scienter.

Dr. Yu's compensation and stock sales: Allegations of a high salary and performance bonuses do not support an inference of fraudulent intent. Dr. Yu sold much less stock during the Class Period than before it, and all her sales were under 10b5-1 plans.

Dr. Yu's departure from FibroGen: Her departure at a logical time, with praise from the CEO, rebuts any inference of wrongdoing or scienter.

April 6, 2021 press release: After Dr. Yu ceased to be a FibroGen employee, new management issued a press release reiterating safety data previously released in 2019 but adding other data previously presented to the FDA as a sensitivity study. Dr. Yu had nothing to do with this press release. She had no duty to disclose what was, on her watch, a sensitivity study. New management's decision to present additional data says nothing about her state of mind.

The Court should dismiss this action as to Dr. Yu.

II. STATEMENT OF THE CASE

Defendant K. Peony Yu, M.D. was employed by FibroGen from December 2008 to March 2021, first as Vice President of Clinical Development and, from April 2016 to December 2020, as Chief Medical Officer. CAC ¶ 23. On December 1, 2020, after 12 years at FibroGen, Dr. Yu and FibroGen announced her retirement as Chief Medical Officer effective December 20, 2020, the same day the FDA said it would approve or reject roxadustat. *Id*. In connection with her retirement, new CEO Enrique Conterno thanked Dr. Yu "for her tremendous contributions as Chief Medical Officer of FibroGen," noting in particular that with "her considerable expertise and leadership, roxadustat was approved in China and Japan for the treatment of CKD anemia with pending regulatory decisions in the US, EU, and additional countries, to potentially serve millions of patients worldwide." Ex. JJ at 2. ("Ex." refers to exhibits to the Kasner Declaration filed with the FibroGen Motion.) Dr. Yu agreed to act as an advisor to Mr. Conterno until March 2021 and, as agreed, she left her employment at FibroGen on March 15, 2021. *Id.* at 1; CAC ¶ 23.

Dr. Yu joins in and incorporates by reference the Introduction and Relevant Facts and Allegations sections in the FibroGen Motion to the extent they relate to the allegations against her.

III. ARGUMENT

A. Count I Does Not Adequately Plead Falsity as to Dr. Yu

To avoid burdening the Court with repetitious arguments, Dr. Yu joins in, incorporates by reference (unless otherwise noted) and does not repeat the arguments made in the FibroGen Motion. Dr. Yu writes separately mainly to address points specific to her that she wishes to underscore.

Because Plaintiffs' allegations are scattershot, it helps to address them by general subject, as follows: roxadustat's efficacy; the prospect of a so-called "Black Box" label; the "non-inferiority margin" the FDA might apply; and the statistical analyses used to assess roxadustat's safety. Of these, the statistical analysis of safety is the most important and warrants the most discussion. The others can be dispensed with briefly, so we will take them up first.

1. Dr. Yu's statements about roxadustat's efficacy were forward-looking expressions of opinion — and true, even in hindsight

Nobody seriously questions the efficacy of roxadustat — not the FDA and not the AdCom.

The FDA, in its brief to the AdCom, stated that roxadustat's "efficacy is not in question" as "[a]ll studies … demonstrated efficacy." Ex. VV at 7. Nobody disagrees. Thus, when Dr. Yu expressed her belief that roxadustat would be shown to be efficacious, her statements cannot be attacked as materially false, even in hindsight.

In December 2018, Dr. Yu allegedly said that roxadustat "achieved superiority in efficacy" and had the "potential to bring clinical benefit over current standard of care." CAC ¶¶ 5, 51, 142-44 (#1). ("#" refers to the numbered statements in the appendix to the CAC, ECF 91-2.) But the CAC pleads nothing calling into question these statements. Similarly, in February 2019, Dr. Yu allegedly expressed the view that roxadustat had shown superiority to epoetin alfa in studies of patients on dialysis. CAC ¶¶ 145-46 (#6). Again, nowhere does the CAC pled anything calling into question these statements. Finally, in March 2020, Dr. Yu allegedly said "'roxadustat can potentially better address CKD anemia than what is currently available to CKD patients on dialysis and those not on dialysis' due to 'the robust efficacy and safety profile demonstrated.'" CAC ¶¶ 187-88 (#44). Again, nowhere does the CAC plead anything calling these statements into question.

Even if the CAC could allege that these statements were not 100% correct in hindsight, that would not state a claim. Dr. Yu was providing her interpretation of the results of the studies. Such "publicly stated interpretation of the results of various clinical studies . . . are essentially no different than opinions" and cannot state a claim for fraud unless Plaintiffs "allege with particularity provable facts to demonstrate that the statement of opinion is both objectively and subjectively false." *In re Sanofi-Aventis Sec. Litig.*, 774 F. Supp. 2d 549, 567 (S.D.N.Y. 2011); *see Rubke v. Capitol Bancorp*, 551 F.3d 1156, 1162 (9th Cir. 2009); *see also Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 183 (2015); *City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Align Tech., Inc.*, 856 F.3d 605, 616 (9th Cir. 2017). The CAC alleges nothing that satisfies either prong of this requirement, let alone both.

2. Dr. Yu's statements about the likelihood of avoiding a "black box" label were forward-looking expressions of opinion, accompanied by appropriate cautions

The CAC alleges that Dr. Yu predicted, on occasions between December 2018 and May 2020, that roxadustat would avoid a "Black Box" label of the sort given to Epogen. CAC ¶¶ 5, 160-

61, 187-91 (#21, 44, 46-49). Roxadustat has not been approved in the United States, so it remains hypothetical what label it would get if approved, but that aside, Dr. Yu's statements all were forward-looking statements and expressions of opinion, not fact, and thus are not actionable unless Plaintiffs can plead facts showing that Dr. Yu did not believe these statements when she made them. *Omnicare*, 575 U.S. at 183; *City of Dearborn*, 856 F.3d at 616; *see Rubke*, 551 F.3d at 1162; *see also In re Sanofi-Aventis Sec. Litig.*, 774 F. Supp. 2d at 567. The CAC does not do this.

In addition, the CAC misrepresents the documents it purports to quote. Contrary to CAC ¶ 5, the press release of December 20, 2018, purportedly quoted says nothing about "Black Box" labeling; the only remark attributed to Dr. Yu is about efficacy. *See* Ex. E at 4. Contrary to CAC ¶¶ 160-61 (#21), at the earnings call of May 9, 2019, Dr. Yu says while she is comfortable with roxadustat's safety and hopes to avoid a Black Box label, "what FDA puts on the label is something that they – that we may not have much control over, except that we have developed a package that we'll target a certain label." Ex. J at 22. Contrary to CAC ¶¶ 187-88 (#44), in the earnings call of March 2, 2020, Dr. Yu simply stated that "we have designed a program to demonstrate safety in comparison to placebo and with the hope and confidence of gaining clean safety label for non-dialysis." Ex. V at 11. And contrary to CAC ¶¶ 189-91 (#46-49), Dr. Yu does not predict roxadustat will avoid a "Black Box" label, while CEO Conterno points out "this is a decision for the regulators." Ex. X at 17. At most these are statements of hope and opinion; they are not actionable as securities fraud.

3. Dr. Yu's statements about the non-inferiority margin that the FDA might choose to apply were forward-looking expressions of opinion – and true when made

As explained in FibroGen's brief, Defendants never said the FDA had agreed to a non-inferiority margin of 1.3 and always made it clear that the non-inferiority margin remained a topic under discussion.[1] Those were truthful statements. Of all the CAC's allegations on this subject (*see,*

[1] The CAC speaks both of the "non-inferiority margin" and the "hazard ratio." The two are related but not the same. At a simple level, the non-inferiority margin is the upper bound that the hazard ratio must not exceed if the drug is to be approved. Strictly speaking, the upper bound of the confidence interval of the hazard ratio must not exceed the non-inferiority margin. The point is that the hazard ratio is a datum, whereas the non-inferiority margin is a benchmark.

e.g., CAC ¶¶ 53-56, 147, 152, 157-59, 171-75), the only one attributed to Dr. Yu is a statement she made on May 9, 2019, that 1.3 is "the conventionally accepted measure in such time to analysis of MACE and MACE+." Ex. J at 8. That statement was true when made and the CAC does not allege otherwise. The FDA's brief of June 14, 2021, to the AdCom, says nothing about 1.25 and repeatedly discusses a non-inferiority margin of 1.3. Ex. VV at 10, 34, 40, 42. At the hearing, Dr. Ellis Unger, Director of the FDA's Office of Cardiology, Hematology, Endocrinology, and Nephrology – responsible for reviewing the roxadustat NDA – said that the choice of a non-inferiority margin was "arbitrary" and "1.3 is reasonable." Ex. XX at 195.

4. Dr. Yu's statements about roxadustat's safety were sincere and truthful forward-looking expressions of opinion

The CAC accuses Dr. Yu of making a number of statements about what studies showed about the safety of roxadustat either compared to placebo (NDD) or Epogen (DD). CAC ¶¶ 5, 143-70 (#1, 6-7, 10, 15-18, 20-21, 23, 26-27); ¶¶ 187-91 (#44, 46-49). All of the statements attributed to Dr. Yu are nothing more than her "publicly stated interpretation of the results of various clinical studies . . . ." *In re Sanofi-Aventis Sec. Litig.*, 774 F. Supp. 2d at 567. Legally, they "are essentially no different than opinions" and cannot state a 10b-5 claim unless Plaintiffs "allege with particularity provable facts to demonstrate that the statement of opinion is both objectively and subjectively false." *Id.* This Plaintiffs have not done and cannot do.

a. Plaintiffs are confused about the statistical analyses employed by FibroGen

That can and should be the end of the story. But there are additional and deeper reasons why Plaintiffs' allegations about safety are wrong. They are wrong because they rest on a fundamentally flawed syllogism, frequently repeated, mantra-like, but never examined or explained. That syllogism goes as follows: Defendants' statements were based on improper statistical analyses; the analyses were improper because they were changed "post hoc"; the analyses' "post hoc" nature was hidden from the investing public; and, therefore, the investing public was misled. Each part of this syllogism is demonstrably wrong.

"Post hoc": As is often the case, use of a Latin phrase obscures rather than clarifies what is meant. "Post" means "after" but "hoc" means … what? The CAC seizes on the use of that phrase

in FibroGen's April 6, 2021 press release and takes it as an admission that something was wrong.

Plaintiffs say they interpret "post hoc" to mean that the statistical analyses were changed or chosen after the pooled data were unblinded and therefore ought to be viewed with suspicion. CAC ¶ 71. But there is no reason for suspicion here. The point of a pre-NDA meeting is to have the drug sponsor and the FDA address specific questions related to the NDA filing to ensure the submission is well-organized and complete. FDA Guidance, *IND Meetings for Human Drugs and Biologics* 8 n.7 (2001), available at https://www.fda.gov/media/70827/download. Because no individual Phase III study was large enough to adequately measure cardiovascular risk, FibroGen and AstraZeneca, consulting with the FDA, planned to pool the safety data from individual Phase III trials. Ex. WW at 14, 44-45, 82. It is not news, or surprising, that the analyses were not settled until the pre-NDA meeting on July 30, 2019. Ex. N at 4-5, 12; Ex. O at 26.

Adding ITT to OT analysis: Years before the unblinding of the NDD studies it was apparent that the dropout rate from the NDD studies (roxadustat versus placebo) was unusually high. Ex. VV at 13. Was it the patients on roxadustat? Or the patients on placebo? Or both? Pre-unblinding, it was impossible to know. But the concern, shared by and discussed between FibroGen and the FDA, was that the high rate of dropouts, if occurring more for one type of treatment under study than the other, would bias the data comparison because of the analytical method chosen – at this point, the "On Treatment" (or "OT") method.[2] Ex. L at 29; Ex. W at 9. With OT, the day patients stopped taking their assigned drug – or alternatively seven days ("OT+7") or 28 days later (or "OT+28") – the analyses disregarded all subsequent events occurring to them (e.g., MACE).

Now suppose (as later proved to be true, after unblinding) this was because patients in the placebo group were disproportionately getting sicker faster. By not analyzing further data on these patients once they stopped taking the placebo, the placebo group suddenly looked healthier. The

[2] "On Treatment" is a method of analysis whereby data from patients who stop taking their assigned drug are not analyzed after treatment with the assigned drug ends. In contrast, "Intent to Treat" continues to track patients until the end of the study (hence ITT is sometimes called "On Study") even if the patients stop taking the assigned drug. For example, if a patient stops taking placebo on Monday and suffers a MACE event (e.g., has a heart attack or dies) on the following Tuesday (eight days later), the MACE event is disregarded for an OT+7 analysis, but included for an ITT analysis.

placebo group was not healthier; it was sicker. But the OT method introduced bias into the study, making them look healthier.

FibroGen realized this. The FDA realized this. FibroGen and the FDA discussed methods to overcome this hurdle. FibroGen told the market via a 10-Q that it was proposing to evaluate safety using an "Intent to Treat" or "ITT" framework to provide a more accurate analysis. Ex. L at 29. The FDA agreed and FibroGen publicly disclosed the agreement in its next 10-Q and next 10-K. Ex. O at 26; Ex. W at 9.

Stratification factors: Before April 6, 2021, Dr. Yu, and FibroGen, never spoke publicly about stratification factors, so there was nothing misstated and nothing to correct. But because Plaintiffs seek to make an issue of this, we shall address it.

Studies like these include all sorts of people who can be divided into all sorts of "strata": men and women; Black and white; residents and nonresidents of the United States; Body Mass Index ("BMI") above or below X; and eGFR scores above or below Y, to mention just a few.[3] All their data go into the pool.[4]

By choosing different stratification analyses, scientists can sometimes determine if there are confounding variables or other factors that distort the results. A confounding variable is something that affects both the dependent variable and the independent variable in a study, thus distorting the connection (or lack thereof) between the two variables. *E.g.,* Federal Judicial Center, *Reference Manual on Scientific Evidence* 221 n.23, 288 (3d ed. 2011). For example, higher ice cream consumption may be correlated with more sunburns, not because ice cream causes sunburns, but because hot sunny days are correlated with both increased ice cream consumption and more sunburns. The hot sunny day is the confounding variable. *See id.* at 219 for other examples.

By proper stratification analysis, one can reduce the impact of such factors and thus gain more precise results for the pool as a whole. This is done, for example, by calculating a hazard ratio

[3] eGFR is a standard measure of kidney function. *See* https://www.kidney.org/atoz/content/gfr

[4] Scientists also care about different strata for their own sake and want to know if a proposed new drug is, say, safe and effective for men but not women, or whites but not Blacks, or low BMI but not high BMI, or high eGFR but not low eGFR. This is sometimes called subgroup analysis. It cannot be performed until the trial is over and the data unblinded. It is not the issue here.

and confidence interval for each strata and then taking the weighted average of each as the result for the whole, with more weight given the strata with less variability. The logic of this is that the strata with less variability are entitled to more weight when estimating the variability of the whole population. *Id.* at 596-97.

b. Nothing Dr. Yu said about safety is actionable

With this background, let's look at what the CAC alleges about Dr. Yu's statements regarding safety. Those statements fall into several categories:

First, Dr. Yu is alleged to have said at earnings conference calls on August 9, 2019 and November 11, 2019 – both after the pre-NDA meeting with the FDA on July 30, 2019 – that FibroGen had a clear understanding of what safety analysis FDA would require, was comfortable with the FDA's guidance, and was comfortable with the data and the agreed-upon analytic methods. CAC ¶¶ 64-65, 177-78, 182, 248 (#34-35); ¶¶ 167-70 (#26-27). Nothing about these statements was untrue, then or now. Contrary to what CAC ¶ 64 alleges, the document ¶ 64 cites does not have Dr. Yu stating that anything was "pre-specified" except that Incident Dialysis was a "pre-specified subgroup of the dialysis-dependent pool." Ex. R at 7. That's a true statement, but it is a statement about subgroups, not stratification factors. *See* footnote 4 above.

Second, Dr. Yu is alleged to have made a series of earlier statements – in 2018 and early in 2019 – to the effect that she is excited about roxadustat's prospects and encouraged by the preliminary safety data. CAC ¶¶ 5, 143-46 (#4, 7). Again, no well-pleaded facts show these statements to be untrue. They represent Dr. Yu's opinion about clinical results and cannot be actionable unless Plaintiffs could allege that Dr. Yu did not believe what she was saying. *In re Sanofi-Aventis Sec. Litig.*, 774 F. Supp. 2d at 567. Plaintiffs have not and cannot do this.

Third, Dr. Yu is alleged to have said, at and after the unblinding of the pooled data, that she thinks the clinical results demonstrate that roxadustat is safe compared to the alternatives. CAC ¶¶ 147-70 (#10, 13, 15-18, 20-21, 23, 26, 27); ¶¶ 187-91 (#46-49). Again, no well-pleaded facts show these statements to be untrue; they are opinions she sincerely held based on results calculated using methods discussed with and agreed upon with the FDA.

Except for CAC ¶ 64 (which is belied by the document it purports to summarize), none of

these allegations has Dr. Yu saying anything about statistical methods let alone stratification factors. These are "inside baseball" subjects of a technical nature that she simply never addressed. Nor was she required to do so. The case law is clear that one need not present the results of sensitivity studies and the like simply because one has chosen to produce the results of one's primary analysis. *Corban v. Sarepta Therapeutics, Inc.*, 868 F.3d 31, 40 (1st Cir. 2017) (holding that "defendants had no legal obligation to loop the public into each detail of every communication with the FDA"); *see also Brody v. Transitional Hosps. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002) (holding that Rule 10b-5 prohibits only misleading and untrue statements, not statements that are incomplete.). Dr. Yu presented the results achieved using statistical methods discussed with and agreed upon by the FDA post-unblinding, and the market knew that. Nothing in the law required Dr. Yu or anyone else at FibroGen to say more.

c. FibroGen's press release of April 6, 2021 does not call into question anything Dr. Yu said about roxadustat's safety

After Dr. Yu had stepped down as Chief Medical Officer and left her employment at FibroGen, new management chose to say more, in the April 6, 2021 press release. That was their right and their prerogative, but it was not required. *In re Rigel Pharms., Inc. Sec. Litig.*, 697 F.3d 869, 880 n.8 (9th Cir. 2012) ("section 10(b) and Rule 10b–5 do not create an affirmative duty to disclose any and all material information; section 10(b) and Rule 10b–5 prohibit only misleading and untrue statements, not statements that are incomplete.") In any event, Dr. Yu had nothing to do with the press release. It was not a statement she wrote, or controlled, or had any input to, and therefore is not something for which she is responsible under the securities laws. *Janus Cap. Grp., Inc. v. First Derivative Traders*, 564 U.S. 135, 142 (2011).

As was their prerogative, new management decided to emphasize to the FDA, and accordingly publicly disclose, additional analyses beyond what by agreement with the FDA had been deemed "the primary cardiovascular safety analyses." Ex. PP at 1. Much as different lawyers will argue the same set of facts in different ways, different management teams can make their own decision as to how best to approach the FDA or any other regulator. This was at most a good-faith disagreement between scientists on which mode of presentation was the best, but the CAC does not

even allege that much, and new management duly disclosed their view of the best mode.[5]

B. Count I Does Not Adequately Plead Scienter as to Dr. Yu

Dr. Yu joins in the scienter arguments made in the FibroGen Motion. For the many reasons stated in that Motion, the CAC's scienter allegations, whether considered holistically or individually, are implausible and do not come close to meeting the exacting standards set by the Private Securities Litigation Reform Act of 1995.

In the 23 paragraphs devoted to scienter (CAC ¶¶ 236-58), aside from allegations about stock sales and compensation, the CAC mentions Dr. Yu's name only three times: once to recount her November 2019 statement that the results disclosed at the conference of the American Society of Nephrology "were based on the analysis plan that we have made with the FDA" (CAC ¶ 248); and two times in allegations attributed to CW3 (CAC ¶¶ 250, 251). None gives rise to an inference that Dr. Yu made any statement attributed to her with any intent to mislead investors.

The November 2019 nephrology conference: The CAC does not allege a single fact suggesting that Dr. Yu did not believe the results discussed at the conference (which she did not attend) and released in the 8-K. The CAC alleges nothing – nor could it truthfully – to suggest that the data presented at the conference and in the 8-K rested on statistical analyses other than the analyses discussed at the pre-NDA meeting in July 2019 and set forth in the NDA itself in December 2019. The only statement attributed to Dr. Yu (in the 8-K) has her saying that:

> The positive efficacy and cardiovascular safety results from these pooled analyses, in a population with a broad range in both CKD and anemia severity in over 8,000 patients across six Phase 3 global trials, reaffirm the potential of roxadustat to improve treatment for anemia in CKD patients. . . . There has not been much progress in treatment approaches for anemia in over 30 years, and more effective, safe, and convenient treatment options for patients are long overdue. We are privileged to be advancing this effort with roxadustat and plan to file the NDA in the U.S. by the end of this quarter for both dialysis and non-dialysis patients with our partner AstraZeneca and the MAA in Europe by the end of first quarter 2020 with our partner Astellas, followed by submissions to other regulatory authorities.

Ex. P at 5. That's a true expression of her opinion and FibroGen's plans; the CAC does not offer a

[5] Nor did it make a difference. The AdCom suggested that new studies be conducted at lower starting doses (instead of relying solely on computer modeling results). The AdCom made it clear that their decision not to approve roxadustat without further studies at lower doses had nothing to do with the statistical analyses performed on MACE endpoint. Ex. XX at 283-86. Neither the AdComm nor the FDA criticized the statistical analyses or considered the different statistical analyses to be of note.

single fact suggesting Dr. Yu thought she was misleading investors when she uttered those words.

April 6, 2021 press release: The CAC suggests that FibroGen's April 6, 2021 press release is an admission that Dr. Yu's November 2019 statement was wrong. Not so. Dr. Yu was not an officer or employee of FibroGen by April 6, 2021. The CAC does not allege she had notice of the press release, or made or adopted it. If the CAC relies on the April 6 press release to infer an earlier fraud, such "admission" cannot be imputed to Dr. Yu. To establish scienter, an admission must be "a statement similar to 'I knew it all along,'" by the speaking defendant. Dr. Yu is not the speaking defendant and she is not saying anything by the April 6 press release. *See Yourish v. Cal. Amplifier*, 191 F.3d 983, 996 (9th Cir. 1999).

CW3's allegations: The allegations of a former AstraZeneca sales employee not alleged to have any science background (CAC ¶ 123 n.10) that Dr. Yu "presented data" at unidentified "boardroom meetings" at some unspecified time (CAC ¶ 124) do not suffice either. The CAC does not allege that CW3 ever spoke directly to Dr. Yu, does not identify the data Yu purportedly presented, or the purpose of the meeting, or who attended, or anything else even remotely suggesting Dr. Yu's state of mind. *See Lloyd v. CVB Financial Corp.*, 2012 WL 12883517, at *12 (C.D. Cal. Aug. 21, 2012) (CW hearsay allegation of "information exchanged at a meeting he did not attend" is "deficient"). CW3's speculation that Dr. Yu "had to have been all over this information" (CAC ¶¶ 124, 250) also is insufficient. "[M]erely speculative awareness of Individual Defendants' knowledge is not enough." *City of Sunrise Firefighters' Pension Fund v. Oracle Corp.*, No. 18-CV-04844-BLF, 2019 WL 6877195, at *19 (N.D. Cal. 2019).

Dr. Yu's compensation: The CAC alleges that Dr. Yu received a high salary plus bonuses tied to achieving milestones. CAC ¶¶ 138, 254. But as FibroGen explains in its motion, nothing about this is suggestive of scienter. FibroGen Mot. at 26-27, citing (among other authorities) *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 1005 (9th Cir. 2009).

Dr. Yu's stock sales under a 10b5-1 plan: Dr. Yu's alleged $2 million in stock sales (CAC ¶¶ 137, 253) do not suggest scienter. Rather, "the plaintiffs must show the trading was in amounts 'dramatically out of line with prior trading practices, at times calculated to maximize the personal benefit from undisclosed inside information…." *Alaska Elec. Pension Fund v. Adecco S.A.*, 434 F.

Supp. 2d 815, 833 (S.D. Cal. 2006). Stock sales alone are never sufficient to create an inference of scienter. *Id.* They may be considered only if they are unusual, suspicious, and out of line with prior trading practices. *Police Ret. Sys. of St. Louis v. Intuitive Surgical, Inc.*, 759 F.3d 1051, 1064 (9th Cir. 2014). But the CAC is entirely silent regarding Yu's prior trading history, "which [is] necessary to determine whether the sales during the Class Period were 'out of line with' historical practices." *Id.* at 1064. Small wonder: during the 24-months before the Class Period began, Dr. Yu sold 212,154 shares; during the 24 months of the Class Period in which she was employed by FibroGen, Dr. Yu sold compared to 39,456 shares. Ex. AAA; *see also* FibroGen Mot. at 25.

All of Dr. Yu's Class Period stock sales were made pursuant to 10b5-1 plans, which negates scienter and supports an inference of good faith. *See City of Royal Oak Ret. Sys. v. Juniper Networks, Inc.*, 880 F. Supp. 2d 1045, 1069 (N.D. Cal. 2012); *Jasin v. VIVUS, Inc.*, 2015 WL 3809357, at *11 (N.D. Cal. June 18, 2015) ("[T]he mere existence of trades made pursuant a Rule10b5–1 trading plan is insufficient alone to give rise to an inference of scienter, and in fact can rebut such an inference.") Nor does the fact that Yu allegedly sold 14% of her total vested holdings indicate scienter. *E.g., Metzler Inv. GMBH v. Corinthian Colls., Inc.*, 540 F.3d 1049, 1067 (9th Cir. 2008) (no indication of scienter where one defendant sold 37% of holdings).

Dr. Yu's departure from FibroGen: Dr. Yu's allegedly "suspicious and abrupt departure" (CAC ¶¶ 72-73, 258) does not support an inference of scienter. "Terminations or resignations of corporate executives are insufficient alone to establish an inference of scienter." *Woolgar v. Kingstone Cos.*, 477 F. Supp. 3d 193, 240-41 (S.D.N.Y. 2020); *see Zucco Partners,* 552 F.3d at 989; *In re UBS AG Sec. Litig.*, No. 07 CIV. 11225 RJS, 2012 WL 4471265, at *18 (S.D.N.Y. 2012) (rejecting scienter "absent additional factual allegations" linking departure to alleged fraud). Far from being suspicious, the circumstances suggest the opposite. Dr. Yu left just ahead of the anticipated FDA approval date for roxadustat. The clinical trials she had led for years had ended, approval was anticipated, and a new CEO had taken over and likely wanted his own team. That she continued, first as an advisor and later as a consultant, undermines any inference that her departure was the result of wronging. *In re NVIDIA Corp. Sec. Litig.*, 768 F.3d 1046, 1062-63 (9th Cir. 2014). So too is the fact that the new CEO heaped praise upon her at the time of her departure for "expertise

and leadership" on roxadustat "with pending regulatory decisions in the US, EU, and additional countries," Ex. JJ at 2, and that FibroGen later announced its internal investigation found no wrongdoing. Ex. YY at 86.

C. Count II Should Be Dismissed

Because the Complaint does not state a primary violation against Dr. Yu, Plaintiffs' "control person" claim under Section 20(a) fails in its entirety. *In re Rigel Pharms., Inc. Sec. Litig.*, 697 F.3d 869, 886 (9th Cir. 2012). In addition, to the extent Count II rests on allegations about acts or omissions occurring after Dr. Yu departed from her role as Chief Medical Officer and ceased to be an employee of FibroGen, any control person allegations against her must fail because the CAC's allegations rebut any argument that she had control.

IV. CONCLUSION

Dr. Yu spoke truthfully and honestly, and without any intent to mislead the FDA or investors. The Consolidated Complaint should be dismissed as to K. Peony Yu, M.D. without leave to amend.

Dated: January 14, 2022

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CERTIFICATE OF SERVICE

I hereby certify under penalty of perjury that on January 14, 2022, I authorized the electronic filing of the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel or parties of record.

/s/Bruce A. Ericson

Bruce A. Ericson